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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,989	02/26/2002	Douglas Alan Miller	45568-00020	7048

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EXAMINER	
MEI, XU	

ART UNIT	PAPER NUMBER
2644	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,989	MILLER ET AL.	
	Examiner	Art Unit	
	Xu Mei	2644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8,16-27 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,16-27 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is responsive to the applicant's amendment dated 09/19/2005.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5, 7-8, 16-27 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer (US 6,788,790) in view of Leysieffer (US 6,554,762) and Nielsen et al (US-6,879,692, hereafter, Nielsen).

Regarding **claims 1 and 20**, Leysieffer '790 generally discloses a system and method for determining the quality of coupling between an implanted hearing aid actuator and an ossicle of a patient's middle ear (column 2, lines 22-31). Leysieffer '790 discloses in Figs. 1-4 and describes at column 6, line 17 -column 8, line 19 fully-implanted embodiments of the

invention, in which test signal generation means (as a separate element 90 in Fig. 1, or comprised in digital signal processor 140 or 141 of Figs. 2 and 3, respectively) are included within the signal processing portion (30) of the implanted hearing aid system, which communicates with a programming system (120) transcutaneously and bidirectionally. Leysieffer '790 discloses in Fig. 5 and describes at column 8, lines 20-47 a partially implanted embodiment of the invention. At column 8, lines 33-37 Leysieffer '790 discloses that the electronic unit (30) of the external system part (210) of the partially implanted hearing aid system of Fig. 5 includes all the electronic components necessary for signal processing and audiometry tone generation, as in the fully-implanted hearing aid embodiments of Figs 1-3. The external system part (210) of the partially-implanted hearing aid system of Fig. 5 thus constitutes a test device, separate from and positionable external to a patient having an implanted hearing aid with an actuator, including a signal generator to generate at least one test signal at a predetermined frequency, wherein said hearing aid passes an electrical signal through the implanted hearing aid actuator in response to said test signal.

Leysieffer '790 does not disclose a measurement device to measure a magnetic field generated by the implanted hearing aid

actuator in response to the electrical signal to generate at least one test measure of the electrical signal; nor [that] a signal processing unit [is configured] to process the at least one test measure to assess at least one performance parameter of the implanted hearing aid.

Although Leysieffer '790 generally indicates a desire to obtain an objective and quantitative measure of the coupling quality of an interface between an implanted hearing aid actuator and a middle-ear ossicle of a patient (e.g., column 2, lines 8-31), only subjective results are obtained by the method and apparatus disclosed, based on conscious (deliberate) patient responses to test signals, or qualitative results by the methods of the prior art described (WO 98/36711), based on electric response audiometry, auditory brainstem response, or electrocochleography.

Leysieffer '762 discloses in Fig. 1, an implantable hearing aid system with means and associated method to objectively obtain a more quantitative measure of the coupling quality of an interface between an implanted hearing aid actuator and a middle-ear ossicle of a patient (a system for assessing the performance of a hearing aid that includes an implanted actuator), which comprises:

a test device including:

a signal generator (DSP 13 in combination with microcontroller 17) to generate at least one test signal at a predetermined frequency, wherein said hearing aid passes an electrical signal through an implanted hearing aid actuator (16) in response to said test signal;

a measurement device (25) to generate at least one test measure (the impedance) of the electrical signal; and

a signal processing unit (13) to process the impedance measure to assess at least one performance parameter of the implanted hearing aid.

Leysieffer '762 does not disclose that the test device is (completely) separate from and positionable external to a patient having the implanted hearing aid, nor that the measurement device measures a magnetic field generated by the implanted hearing aid actuator; rather, the system of Leysieffer '762 determines the test measure (actuator impedance) by measuring a voltage drop across a current sampling resistor ("Rm" in Fig. 2) to determine the associated current, and calculates the impedance as the quotient of the applied voltage (to the actuator) and the thus-determined current through the actuator. In Fig. 11, Leysieffer '762 discloses an embodiment of the invention in which the hearing aid system is a partially-implanted type, similar to that of Fig. 5 of Leysieffer '790,

including the elements of Fig. 1 (of the '762 patent, sans telemetry system 20), in which a passive electronics module (74) is implanted along with a transducer (16 or 36), and in which the remainder of the electronics are disposed in an external unit (76). Some specific details of this embodiment are described at column 20, line 64 through column 21, line 13, where it is disclosed that the impedance measuring system (25) of Fig. 1 is included in the implanted portion of the hearing aid system. With regard to the embodiment of Fig. 11, Leysieffer '762 does not disclose any specific details of the interconnection to a programming system or how the impedance measurement data is presented or interpreted, other than reciting at column 21, lines 9-13, "The electronic module 77 and the modulator/transmitter unit 75 include the necessary telemetry unit for transmission of the impedance measuring data to the external module 76 for further evaluation." One of ordinary skill in the art would reasonably assume that the external unit (76) connects to a programming system, equivalent to that of Figs. 1, 6, and 7 (22), except in this case the connection could be a direct wire connection, rather than a wireless transcutaneous electrical interface, as illustrated in Fig. 5 and described at column 8, lines 37-42 of Leysieffer '790.

voltage values to the external portion of the hearing aid system.

Nielsen discloses in Fig. 1, a hearing aid system (Fig. 1) with self-test capability including a pick-up coil for picking up a significant magnetic field generated by a output transducer 38 (col. 5, lines 58-62) for testing the hearing aid device (see also claim 20) for the purpose of suppressing such magnetic field effect on the hearing aid.

It would have been obvious to one of ordinary skill in the art at the time the present invention was made to employ the magnetic field sensing circuit of Nielsen, located in the external test unit (210) of the partially-implanted hearing aid system of Fig. 5 of Leysieffer '790, to determine the impedance of the implanted actuator (20), according to the teachings of Leysieffer '762 and common knowledge in the art as described above, to create a test system that does not require a bidirectional interface for the implanted portion of the hearing aid system to transmit measurement data back to external portion, thus simplifying the structure of implanted portion, reducing its power requirements, and potentially improving its reliability, and perhaps most importantly, not requiring the replacement of an existing implant in patients already having a partially-implanted hearing aid system of the type depicted in

At the time the present invention was made, it was conventional to construct partially-implanted hearing aid systems such as that of Fig. 5 of Leysieffer '790 with most of the circuitry contained in the external portion, and with a minimum of componentry included in the implanted portion (e.g., receiving coil, demodulator, and transducer, as described and illustrated in US Patent 5,795,287 to Ball et al., cited by Leysieffer '790 at column 8, lines 29-33); such minimally-complex construction of the implanted portion of the hearing aid system was well known to provide advantages such as reduced size and mass, reduced power transfer requirement across the inherently-inefficient inductive transcutaneous power interface (and thus improved energy efficiency), and probably most importantly, improved reliability of the implanted portion, which is difficult and costly to service or replace. In view of this common knowledge in the art and the teachings of Leysieffer '762, one of ordinary skill would have sought alternative methods to obtaining externally a measure of the actuator impedance of a partially-implanted hearing aid system of the type taught by Leysieffer '790 without requiring in the implanted portion of the hearing aid system additional circuitry for actuator current and voltage sensing and a bidirectional communication interface to communicate the measured current and

Fig. 5 of Leysieffer '790 (which does not include an impedance measuring system), and further provide more accurate signal measurement for testing the implanted hearing device of Leysieffer by including the additional magnetic field sensing signal as shown by Nielsen, thus reducing such magnetic field effect on the hearing aid itself.

Further regarding **claim 1**, the inherent normal method of testing the quality of coupling of the actuator to a component of a patient's auditory system according to the system of Fig. 5 of Leysieffer '790, modified according to the teachings of Leysieffer '762 and Nielsen as described above, would comprise positioning a test measurement device (210) external to a patient having an implanted hearing aid (220) that includes an actuator (20), wherein the test device is separate from said hearing aid (as Applicant claims "an implanted hearing aid", any part of the system that is not implanted, such as external portion 210 of Leysieffer '790 Fig. 5, is "separate from the hearing aid", as broadly as claimed); utilizing the test measurement device to obtain at least one measure of a magnetic field generated by the actuator in response to a resultant electrical signal passing through the actuator (Leysieffer '762, claim 13); and employing the at least one magnetic field measure to assess the performance of the actuator (Leysieffer '762,

claim 1).

Regarding **claims 2-5 and 21-24**, Leysieffer '762 discloses at column 6, lines 46-63 that means are provided for objectively determining the quality of coupling between the output transducer (actuator) and the coupled auditory element based on the measured impedance. Objective determination based on measured quantities inherently comprises comparing the measured quantities to one or more predetermined ranges. Also, in a digital system, as generally disclosed by Leysieffer '762, an analog test measure must be converted to a digital value by an analog-to-digital (A-to-D) converter; such an A-to-D conversion inherently comprises comparing the (analog) test measure to a plurality of (at least partially non-overlapping) predetermined ranges (the ranges corresponding to the set of possible digital values producible by the A-to-D converter according to its resolution). This comparison is performed to assess performance parameters of the hearing aid and implanted actuator. Leysieffer '762 discloses at column 13, line 66 through column 14, line 7 that the microcontroller of the hearing aid system communicates bi-directionally with an external programming system, which can advantageously be a PC-based system with the corresponding programming, processing, display, and

administration software. Although Leysieffer '762 does not explicitly disclose the detailed nature of the output provided to the operator of the system, one of ordinary skill in the art would conclude that means are included within the programming system to provide a user-interface output, via a display of the PC-based programming system, indicative of whether the measured quantities are within predetermined ranges. Leysieffer '762 discloses at column 8, lines 23-29 that impedance is measured at resonance frequencies. Objective determination based on measured quantities inherently comprises comparing the measured quantities (magnetic field measures in the system of Leysieffer '762, modified according to the teachings of Leysieffer '790 and Nielsen) to one or more predetermined ranges (e.g., the graduations of an arbitrary scale) using appropriate means; and testing the quality of the actuator coupling to an auditory element as disclosed by Leysieffer will inherently indicate if the hearing aid is operational and thus will implicitly facilitate assessment of the operability of the hearing aid as alternatively claimed in claim 21or 23 and claim 2 or 4. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to compare the measured impedance value obtained by the system of Leysieffer '790, modified according to the teachings of

Leysieffer '762 and Nielsen as described above with regard to claims 1 and 20, with any desired number of predetermined ranges which are at least partially non-overlapping, utilizing appropriate means, in order to categorize the test results. Further, it would have been obvious to make a plurality of ranges at least partially non-overlapping, since if the ranges were not at least partially non-overlapping, they would be identical and the results of the comparisons would duplicate each other. Also, one of ordinary skill in the art would conclude that means are included and utilized in the system of Leysieffer '762 to provide an output indicative of whether the measured quantities are within the predetermined ranges, otherwise the results of the measurements would be useless and the device would be non-functional with respect to the desired test function.

Regarding **claims 7 and 25**, as broadly as claimed, any test signal has a frequency that is within some (predetermined) range of a resonant frequency of an actuator. Additionally, Leysieffer '762 discloses at column 8, lines 23-29 that impedance is measured at resonance frequencies, which inherently requires the signal generator to output test signals at those

resonant frequencies.

Regarding **claim 8**, in the partially-implanted hearing aid system of Fig. 5 of Leysieffer '790, modified according to the teachings of Leysieffer '762 and Nielsen, the test device (comprising an external signal processor and programming system of the hearing aid system, generally as 30 and 120 of Fig. 5 of Leysieffer '790) is "selectively interconnected" to an external transmitter (170) of the hearing aid (the transmitter or transmitter type is presumably selected to operate properly with the other elements of the system to which it is interconnected), and according to the general disclosures of Leysieffer ('790 and '762), at least one predetermined test signal is transmitted from the test device (comprising 30 and 120 of Fig. 5 of '790 patent) to the external transmitter (170); and the at least one test signal is inductively coupled between the external transmitter and a subcutaneous coil (190) of the hearing aid.

Regarding **claim 16**, the normal method of use of the remote current sensor of Durant according to Fig. 1a would include obtaining a first measurement of the magnetic field at a first location (the location of sensor A, element 20); obtaining a second measurement of the magnetic field at a second location

(the location of sensor B, element 22); providing an output indicative of the first and second measurements of the magnetic field (the output including a measure of the current, "I" and the distance, "r" from sensor A (20) to the source of the magnetic field as described at column 4, lines 1-12). In the system of Leysieffer '790, modified as described above to include the remote current sensor of Durant, it would have been obvious to one of ordinary skill in the art at the time the present invention was made to use the calculated distance output, "r" to determine a desired position of the test device that is as close as possible to the source of the magnetic field in order to achieve maximum accuracy in the obtained current measurement.

Regarding **claims 17 and 26**, Leysieffer '762 discloses at column 8, lines 1-17 that impedance measurements are made at frequencies extending over the entire transmission frequency range of the output transducer (actuator), which inherently requires providing a plurality of predetermined test signals having different frequencies distributed across a predetermined frequency range to cause a corresponding plurality of electrical signals to pass through the actuator, wherein the plurality of predetermined test signals are at a corresponding plurality of

different frequencies distributed across a predetermined frequency range.

Regarding **claims 18 and 27**, in the system of Leysieffer '790, modified according to the teachings of Leysieffer '762 and Nielsen as described above, the system would be configured to measure a plurality of magnetic field measures corresponding to the plurality of electric signals passing through the actuator and the normal method of utilizing the test device would include using the test device to obtain a plurality of magnetic field measures corresponding to the plurality of electrical signals passing through the actuator.

2. Regarding **claim 19**, Leysieffer '762 discloses at column 8, lines 23-31, detecting (and thus identifying) the spectral distribution of resonance frequencies of the transducer in the course of the impedance measured as a function of the frequency of the stimulation signal.

Regarding **claim 37**, in the partially implanted hearing aid system and method of Fig. 5 of Leysieffer '790, modified according to the teachings of Leysieffer '762 and Nielsen as described above with regard to claim 20, the test device

(comprising elements 30 and 120) includes said signal processing unit (30).

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Taenzer et al discloses an apparatus and method provided for monitoring magnetic hearing system by detecting magnetic field outputted by the hearing system.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xu Mei whose telephone number is 571-272-7523. The examiner can normally be reached on Monday-Friday (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vivian Chin can be reached on 571-272-7848. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xu Mei
Primary Examiner
Art Unit 2644
12/08/2005